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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/500,634	01/24/2005	Yoram Sela	SELA5	3015
1444	7590	04/14/2006	EXAMINER	
BROWDY AND NEIMARK, P.L.L.C. 624 NINTH STREET, NW SUITE 300 WASHINGTON, DC 20001-5303			VU, JAKE MINH	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 04/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/500,634	Applicant(s) SELA, YORAM	
	Examiner Jake M. Vu	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment filed on 01/24/06, and Foreign Priority Papers filed on 07/02/04. Claims 1-30 are pending in the instant application.

Response to Arguments

Applicant's arguments, filed on 01/24/06, with respect to the 35 USC §103 rejection have been fully considered and are persuasive. The 35 USC §103 rejection has been withdrawn.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 19, and 24-26 are rejected under 35 U.S.C. 102(b) as being anticipated by JEARY et al (WO 00/71099).

Applicant claims a composition comprising of: an active agent, such as venlafaxine; and a binder, such as hydroxypropyl cellulose, coated on a sugar nonpareil inert core, which enable the controlled release of the active agent over an extended time period. Additional limitation includes an additional polymeric layer composes of Eudragit and a plasticizer, such as diethyl phthalate.

JEARY disclosed a composition comprised of: an active agent, such as venlafaxine (pg. 5, line 13-15) and a binder (pg. 7, line 16), such as hydroxypropyl cellulose (pg. 8, line 26) coated on a sugar nonpareil inert core (pg. 10, line 20-21), which enabled the controlled release of the active agent over an extended time period, such as a 24 hour period (see abstract). Additional disclosure includes an additional polymeric layer (pg. 8, line 16-17) composed of Eudragit (pg. 9, line 16-22) and a plasticizer (pg. 11, line 6-8), such as diethyl phthalate (pg. 11, line 26-27).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over JEARY et al (cited supra) in view of McTEIGUE et al (US 6,149,943) and KAMADA (US 5,505,983).

Applicant claims a composition comprising of: an active agent, such as venlafaxine; and a binder, such as hydroxypropyl cellulose, coated on a sugar nonpareil inert core, which enable the controlled release of the active agent over an extended time period. Additional limitations include: an additional polymeric layer composes of

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Eudragit and a plasticizer, such as diethyl phthalate; and a protection layer, such as hydroxypropyl methylcellulose.

As discussed above, JEARY disclosed a composition comprised of: an active agent, such as venlafaxine (pg. 5, line 13-15) and a binder (pg. 7, line 16), such as hydroxypropyl cellulose (pg. 8, line 26) coated on a sugar nonpareil inert core (pg. 10, line 20-21), which enabled the controlled release of the active agent over an extended time period, such as a 24 hour period (see abstract). Additional disclosure includes an additional polymeric layer (pg. 8, line 16-17) composed of Eudragit (pg. 9, line 16-22) and a plasticizer (pg. 11, line 6-8), such as diethyl phthalate (pg. 11, line 26-27).

JEARY does not disclose using a protection layer such as hydroxypropyl methylcellulose.

McTEIGUE disclosed a composition comprised of: an active drug; binder (col. 6, line 64); Eudragit and cellulose (col. 4, line 27-36) coated on a microcrystalline nonpareil core (see abstract). Additional disclosure includes: prior art had used sugar core (col. 3, line 18).

KAMADA incorporated by McTEIGUE (col. 3, line 17) disclosed using a moisture-protection layer comprised of hydroxypropyl methylcellulose (col. 9, line 60-62).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate a protection layer. The person of ordinary skill in the art would have been motivated to make that modification, because the protection layer would decrease friability and moisture, and reasonably would have expected success

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because all the references dealt with controlled release of an active drug by coating onto a nonpareil core.

The references do not specifically teach adding the ingredients in the amounts claimed by Applicant. The amount of a specific ingredient in a composition is clearly a result effective parameter that a person of ordinary skill in the art would routinely optimize. Optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ and reasonably would expect success. It would have been customary for an artisan of ordinary skill to determine the optimal amount of each ingredient to add in order to best achieve the desired results. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization of ingredient amount would have been obvious at the time of Applicant's invention.

Telephonic Inquiries

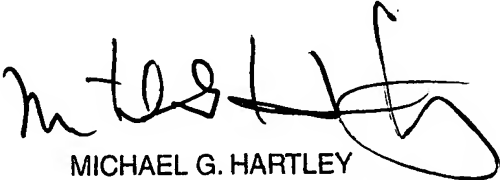
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jake M. Vu whose telephone number is (571) 272-8148. The examiner can normally be reached on Mon-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jake M. Vu, PharmD, JD
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MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER